

## **Remarks / Arguments**

### **Current amendments**

Following the suggestions in the Office Action, the following amendments are currently brought:

New claim 21 has now been redrafted so as to delete the reference to the 'French Pharmacopoeia'.

New claim 27 is currently amended, so as to specify again the particle size distribution below 30 microns, as was the case in the original claim 7.

It is respectfully submitted that the pending claims comply with 35 USC 112.

**Claims 1-20 are rejected under 35 USC 103(a) as being unpatentable over Liu et al. (US 6,465,009) in view of Schmitz et al. (US 6,079,968).**

This rejection is respectfully traversed.

It is respectfully submitted that the combination of the Liu et al. patent with the Schmitz et al. patent would neither teach nor suggest the presently claimed matter:

As stated in the previous Office Action, the Liu et al. patent does not teach methods of manufacturing tablets wherein the lubricant is entirely or mostly applied to the outer surface of the tablet. Moreover, it is herewith submitted, that the Liu et al. patent does not teach nor suggest tablets having such a characteristic.

The rejection under 103(a) is based upon the assumption that the skilled artisan would have easily combined the teachings from the Liu et al. patent with those of the Schmitz et al. patent. The Schmitz et al. patent relates to a device for spraying a lubricant.

This rejection is respectfully traversed: if the teachings from the Schmitz et al. patent are undisputable, it is far from obvious that the one of ordinary skill would have used these teachings in combination of those from the Liu et al. patent. As a contrary, **there is no incentive for the skilled artisan to expressly apply the teachings from the Schmitz et al. patent to the very tablets described in the Liu et al. patent.** The Schmitz et al. patent is concerned with an improved device in order to supply lubricant to a tableting press, as stated in column 1, lines 45-51. However, the Schmitz et al. patent remains silent about which kinds of tablets are to be manufactured using this device, and does not relate to the specific field of orally dispersible tablets. Conversely, the Liu et al. patent is altogether silent about manufacturing methods. **Sh** uld the skilled artisan have decided to combine these teachings, then possibly there could have been some expectation of success. However,

**with out any further indication**, the one of ordinary skill **would absolutely not have combined** the device from the Schmitz et al. patent with the tablets from the Liu et al. patent.

In addition, the object of the present invention achieves the following totally unexpected effects. As recited in claim 1, and in the description on page 2, lines 3-9, the tablet of the invention is sufficiently hard to enable it to be removed easily from the blister in which it is packaged, by tearing, perforating or breaking the seal of the blister pack by pushing the tablet, **with a substantially reduced risk of the tablet breaking**. What's more, as mentioned on page 5, lines 8-27, the tablets of the invention are particularly suitable for packaging in **blisters composed entirely of aluminium**; the tablets of the present invention enable **child safety standards** to be met, as it can be kept in **doubly protected blisters**; it is also possible to package the tablets object of the present invention in blisters made entirely of aluminium of a substantial thickness providing complete **moisture-proofing**, thus enabling a commercial product to be obtained which has **excellent storage properties**. These features and advantageous effects are neither taught nor even suggested by the Liu et al. patent, nor by the Schmitz et al. patent either. This makes the present invention non-obvious over the Liu et al. and the Schmitz et al. patents.

It is thus respectfully requested that the above cited rejection be withdrawn.

**Claims 1-20 are rejected under 35 USC 103(a) as being unpatentable over Liu et al. (US 6,465,009) in view of Schmitz et al. (US 6,079,968) and Valentine et al. (US 4,684,534).**

This rejection is respectfully traversed.

As stated in the Office Action, the Valentine et al. patent is concerned with lubricant particle size.

However, neither is there an incentive for the skilled artisan to combine such lubricant particles with the very device from the Schmitz et al. patent, nor is it obvious to use such particles for making tablets as disclosed in the Liu et al. patent.

Moreover, it is very unlikely that one of **ordinary** skill would combine **three** different teachings at the same time. As a contrary, the fact that three documents are to be combined to arrive at the present invention is a clear indication that the tablets of the invention indeed are non-obvious.

Furthermore, the Valentine et al. patent is also silent with respect to the unexpected effects described in the above section. As a result, the present invention can only be non-obvious.

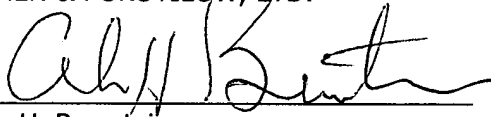
It is thus respectfully requested that the above cited rejection be withdrawn.

In view of the above, it is respectfully submitted that the application is now in proper form for allowance.

Respectfully submitted,

CAESAR, RIVISE, BERNSTEIN,  
COHEN & POKOTILOV, LTD.

By:



Alan H. Bernstein  
Registration No. 19,315  
Seven Penn Center, 12<sup>th</sup> Floor  
1635 Market Street  
Philadelphia, PA 19103-2212  
215/567-2010  
Attorney for Applicants  
Customer No. 03000

Dated: February 25, 2004